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U.S. DISTRICT COURT E.D.N.Y.

★ MAR 24 2011 ★

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
JEAN ALIX and PHILIP ALIX,

Plaintiffs,

-against-

ELI LILLY AND COMPANY, XANODYNE
PHARMACEUTICALS, INC., VINTAGE
PHARMACEUTICALS, INC., QUALITEST
PHARMACEUTICALS, and ENDO
PHARMACEUTICALS, INC.

Defendants.
-----X

BROOKLYN OFFICE

Civil Action

Index No:

CV 11-1456

COMPLAINT

AND JURY DEMAND

SUMMONS ISSUED

**BIANCO, J.
TOMLINSON, M.J.**

Plaintiffs, by their attorneys, **PARKER WAICHMAN ALONSO LLP**, on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Eastern District of New York.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff, JEAN ALIX, who was prescribed, purchased and correctly used DARVOCET, also known generically as Propoxyphene Napsylate and Acetaminophen.

5. Plaintiff PHILIP ALIX, at all times relevant hereto, was and is the spouse of Plaintiff JEAN ALIX.

6. Defendants, ELI LILLY AND COMPANY, XANODYNE PHARMACEUTICALS, INC, QUALITEST PHARMACEUTICALS, VINTAGE PHARMACEUTICALS INC., and ENDO PHARMACEUTICALS, INC. (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed DARVOCET for use as a prescription pain management medication.

7. Defendants concealed their knowledge of DARVOCET's defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

8. When warning of safety and risks of DARVOCET, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that DARVOCET had been tested and was found to be safe and/or effective for its indicated use.

9. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase DARVOCET for use as a prescription pain management medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

10. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning DARVOCET's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other prescription pain management medications, which does not entirely and/or necessarily apply to the DARVOCET whatsoever.

11. As a result of the defective nature of DARVOCET, those persons who use and/or used and relied on DARVOCET have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

12. Plaintiff herein has sustained certain of the above health consequences due to her use of DARVOCET.

13. Defendants concealed its knowledge of the defects in its product from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

14. Consequently, Plaintiff seeks compensatory damages as a result of her use of DARVOCET, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

14. Plaintiff, JEAN ALIX, is a natural person and is a resident of the State of New York.

15. Prior to May 2010, plaintiff, JEAN ALIX, did not have a pre existing cardiac history and had never suffered a cardiac arrhythmia.

16. Plaintiff, JEAN ALIX, was prescribed DARVOCET for pain management in or about August 2006.

17. As result of using Defendants' drug DARVOCET, Plaintiff JEAN ALIX, was caused to suffer cardiovascular injuries and cardiac arrhythmias, including but limited to, atrial flutter in or about May 2010.

18. Plaintiff, JEAN ALIX used DARVOCET in the manner in which it was prescribed to her at or about the time she suffered cardiovascular injuries and arrhythmias, including but limited to, atrial flutter, in or about May 2010.

19. In order to treat her arrhythmia and life threatening cardiac condition, plaintiff, JEAN ALIX, underwent numerous invasive cardiac procedures including cardiac ablation.

20. Plaintiff, JEAN ALIX, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong cardiac monitoring, treatment and medications.

21. The injuries and damages sustained by Plaintiff, JEAN ALIX, were caused by Defendants' drug DARVOCET.

22. Plaintiff, PHILIP ALIX, is a natural person and is a resident of the State of New York.

23. Plaintiff, PHILIP ALIX, was and is the lawful spouse of Plaintiff, JEAN ALIX, and as such, was entitled to the comfort, enjoyment, society and services of his spouse.

PARTY DEFENDANTS

24. Upon information and belief, Defendant ELI LILLY AND COMPANY, and at all relevant times was, a corporation organized under the laws of the State of Indiana, with its principal place of business located in the State of Indiana.

25. Upon information and belief, at all relevant times Defendant ELI LILLY AND COMPANY, has transacted and conducted business in the State of New York and derived substantial revenue from interstate commerce.

26. Upon information and belief Defendant ELI LILLY AND COMPANY, expected or should have expected that its acts would have consequences within the United States of America, and Sunnyside, New York and within the confines of the Eastern District of New York in particular and derived substantial revenue from interstate commerce.

27. Upon information and belief, and at all relevant times Defendant ELI LILLY AND COMPANY, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription management medication.

28. Upon information and belief, Defendant ELI LILLY AND COMPANY, was the original holder of the approved New Drug Application for DARVOCET.

29. Upon information and belief, AAIPHARMA SERVICES, obtained the rights to the approved New Drug Application for DARVOCET from Defendant ELI LILLY AND COMPANY in or around February 2002.

30. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., obtained the rights to the approved New Drug Application for DARVOCET from Defendant AAIPHARMA SERVICES in or around May 2005.

31. Upon information and belief, Defendant XANODYNE HARMACEUTICALS,

INC., and at all relevant times was and is a corporation organized under the laws of the State of Kentucky, with its principal place of business located in the State of Kentucky.

32. Upon information and belief, at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., has transacted and conducted business in the State of New York and derived substantial revenue from interstate commerce.

33. Upon information and belief Defendant XANODYNE PHARMACEUTICALS, INC., expected or should have expected that its acts would have consequences within the United States of America, and Sunnyside, New York and within the confines of the Eastern District of New York in particular and derived substantial revenue from interstate commerce.

34. Upon information and belief, and at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription management medication

35. Upon information and belief, Defendant XANODYNE HARMACEUTICALS, INC., is the holder of approved New Drug Application for DARVOCET.

36. Upon information and belief, Defendant VINTAGE PHARMACEUTICALS INC. is an Alabama corporation with its principal place of business located at 120, 130, and 150 Vintage Road NE, Huntsville, AL 35811.

37. Upon information and belief, Defendant VINTAGE PHARMACEUTICALS INC. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Propoxyphene Napsylate and Acetaminophen, which is a generic form of DARVOCET.

38. Upon information and belief and at all relevant times, Defendant QUALITEST PHARMACEUTICALS conducted business in the State of New York and derived substantial revenue from interstate commerce.

39. Upon information and belief, Defendant QUALITEST PHARMACEUTICALS is an Alabama corporation with its principal place of business located at 120, 130, and 150 Vintage Road NE, Huntsville, AL 35811.

40. Upon information and belief, Defendant QUALITEST PHARMACEUTICALS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Propoxyphene Napsylate and Acetaminophen, which is a generic form of DARVOCET.

41. Upon information and belief and at all relevant times, Defendant QUALITEST PHARMACEUTICALS conducted business in the State of New York and derived substantial revenue from interstate commerce.

42. Defendants VINTAGE PHARMACEUTICALS, INC. and QUALITEST PHARMACEUTICALS herein after collectively referred to as VINTAGE QUALITEST PHARMACEUTICALS.

43. Upon information and belief and at all relevant times, Defendant VINTAGE QUALITEST PHARMACEUTICALS, is the holder of ANDA for Propoxyphene Napsylate and Acetaminophen, including, but not limited to, ANDA numbers 074843 in or around February 12, 1997.

44. Upon information and belief, Defendant ENDO PHARMACEUTICALS INC. is a Pennsylvania corporation with its principal place of business located at 100 Endo Boulevard,

Chadds Ford, PA 19317.

45. Upon information and belief, Defendant ENDO PHARMACEUTICALS, INC. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Propoxyphene Napsylate and Acetaminophen, which is a generic form of DARVOCET.

46. Upon information and belief and at all relevant times, Defendant ENDO PHARMACEUTICALS, INC. conducted business in the State of New York and derived substantial revenue from interstate commerce.

47. Upon information and belief Defendant ENDO PHARMACEUTICALS, INC acquired VINTAGE/QUALITEST PHARMACEUTICALS in December 2010.

48. Upon information and belief, and at all relevant times Defendant, ELI LILLY AND COMPANY, licensed, amongst other things, its “know-how” and “trademarks to commercialize Darvon and Darvocet and any other pharmaceutical product containing the active pharmaceutical ingredient Propoxyphene in the United States” to other entities including but not limited to Defendants XANODYNE PHARMACEUTICALS, INC and VINTAGE PHARMACEUTICALS INC., QUALITEST PHARMACEUTICALS, and ENDO PHARMACEUTICALS, INC..

FACTUAL BACKGROUND

49. At all relevant times, Defendants was and remains in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed DARVOCET for use as a prescription pain management medication.

50. At all times relevant, Defendants focused its sales on pain management products including DARVOCET because the area of pain management offers attractive commercial opportunities in significant markets in the United States, see <http://www.xanodyne.com/strategy.asp> (as of December 9, 2010).

51. At all times relevant, Defendants affirmatively decided not to take part in full discovery research of its products because Defendants believed that it was more beneficial for it to advance products quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market, see <http://www.xanodyne.com/strategy.asp> (as of December 9, 2010).

52. By using a strategy of moving its products through the research and development process expeditiously Defendants believes it can reach its goal of becoming a leading integrated specialty pharmaceutical company that develops and commercializes new products for significant markets in pain management, <http://www.xanodyne.com/strategy.asp> (as of December 9, 2010).

53. About 10 million people in the U.S. received prescriptions for DARVOCET and Propoxyphene related drugs, in 2009 according to the FDA.

54. Upon information and belief, Adverse Event data maintained by the FDA indicates staggering, serious Adverse Events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

55. Defendants ignored the correlation between the use of DARVOCET and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

56. In June 2009, the European Medicines Agency (EMA) recommended that the marketing authorizations for Propoxyphene be withdrawn across the European Union for safety concerns.

57. Despite being petitioned by public interest groups to investigate whether DARVOCET was linked to serious and potentially fatal heart arrhythmias, Defendants refused to do so until July 2009, when they were ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of DARVOCET on the heart.

58. Plaintiff, JEAN ALIX, experienced a cardiac arrhythmia as a result of taking DARVOCET in May 2010.

59. The results of the study ordered by the FDA indicated that even when taken at recommended doses, Propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

60. On November 19, 2010, the FDA announced that Defendants, Xanodyne Pharmaceuticals, Inc., had agreed to halt all U.S. Marketing of DARVOCET after it was determined that the drug's benefits were outweighed by the risks associated with its use, specifically the potential of the drug to cause serious and potentially fatal heart arrhythmias.

61. The use of DARVOCET creates unique and dangerous risks compared to other prescription pain management medications. These risks include, including inter alia heart

arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

62. The Defendants did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been repeated by the medical community.

63. By reason of the foregoing, Plaintiff has developed and/or is at extremely high risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

64. Plaintiff has endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

65. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' drug DARVOCET.

FEDERAL REQUIREMENTS

66. Defendants had an obligation to comply with the law in the manufacture, design, and sale of DARVOCET.

67. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

68. With respect to the prescription drug DARVOCET, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.
- b. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for DARVOCET and such deviations are not plainly stated on their labels.
- c. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.
- d. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and

understood by the ordinary individual under customary conditions of purchase and use.

- e. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.
- f. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- g. The prescription drug DARVOCET does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

- h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.
- i. The prescription drug DARVOCET is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.
- j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of DARVOCET cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.
- k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug DARVOCET.
- l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug DARVOCET are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.
- m. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.
- n. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

- o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug DARVOCET and other drugs in the same pharmacologically active and chemically related class.
- p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug DARVOCET.
- q. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.
- r. The prescription drug DARVOCET violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.
- s. The prescription drug DARVOCET violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.
- t. The prescription drug DARVOCET violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or

reproducibility of test methods have not been properly established and documented.

- u. The prescription drug DARVOCET violates 21 CFR § 211.165 in that the prescription drug DARVOCET fails to meet established standards or specifications and any other relevant quality control criteria.
- v. The prescription drug DARVOCET violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug DARVOCET were not followed.
- w. The prescription drug DARVOCET violates 21 CFR § 310.303 in that the prescription drug DARVOCET is not safe and effective for its intended use.
- x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.
- y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug DARVOCET as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.
- z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug DARVOCET, and evaluating the cause of the adverse event.
- aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-

up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

- bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.
- cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report followup.”
- dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug DARVOCET or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.
- ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

69. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants negligent *per se*.

**AS AND FOR THE
FIRST CAUSE OF ACTION
AGAINST THE DEFENDANTS
(NEGLIGENCE)**

70. Plaintiffs repeat, reiterate and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

71. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of DARVOCET into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

72. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of DARVOCET into interstate commerce in that Defendants knew or should have known that using DARVOCET created a high risk of unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished

enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

73. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not DARVOCET was safe for use; in that Defendants herein knew or should have known that DARVOCET was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling DARVOCET without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of DARVOCET;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, DARVOCET;
- (g) Failing to test DARVOCET and/or failing to adequately, sufficiently and properly test DARVOCET.
- (h) Negligently advertising and recommending the use of DARVOCET without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that DARVOCET was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently representing that DARVOCET had equivalent safety and efficacy as other prescription pain management medications;
- (k) Negligently designing DARVOCET in a manner which was dangerous to its users;
- (l) Negligently manufacturing DARVOCET in a manner which was dangerous to its users;

- (m) Negligently producing DARVOCET in a manner which was dangerous to its users;
- (n) Negligently assembling DARVOCET in a manner which was dangerous to its users;
- (o) Concealing information concerning FDA warnings from the Plaintiff in knowing that DARVOCET was unsafe, dangerous, and/or non-conforming with FDA regulations;
- (p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of DARVOCET compared to other prescription pain management medications.

74. Defendants under-reported, underestimated and downplayed the serious dangers of DARVOCET.

75. Defendants negligently compared the safety risk and/or dangers of DARVOCET with other prescription pain management medications.

76. Defendants was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of DARVOCET in that it:

- (a) Failed to use due care in designing and manufacturing DARVOCET so as to avoid the aforementioned risks to individuals when DARVOCET was used for prescription pain management;
- (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of DARVOCET;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of DARVOCET;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning DARVOCET;

- (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (b) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of DARVOCET;
- (g) Failed to warn Plaintiff, prior to actively encouraging the sale of DARVOCET, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;
- (h) Were otherwise careless and/or negligent.

77. Despite the fact that Defendants knew or should have known that DARVOCET caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell DARVOCET to consumers, including the Plaintiff.

78. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

79. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

80. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

81. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

82. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
SECOND CAUSE OF ACTION
AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)**

83. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

84. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed DARVOCET as hereinabove described that was used by the Plaintiff.

85. That DARVOCET was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

86. At those times, DARVOCET was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

87. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of DARVOCET.

88. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

89. At all times herein mentioned, DARVOCET was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

90. Defendants knew, or should have known that at all times herein mentioned its DARVOCET was in a defective condition, and was and is inherently dangerous and unsafe.

91. At the time of the Plaintiff's use of DARVOCET, DARVOCET was being used for the purposes and in a manner normally intended, namely for pain management.

92. Defendants with this knowledge voluntarily designed its DARVOCET in a dangerous condition for use by the public, and in particular the Plaintiff.

93. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

94. Defendants created a product unreasonably dangerous for its normal, intended use.

95. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that DARVOCET left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

96. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by

Defendants reached its intended users in the same defective and unreasonably dangerous condition in which the Defendants' drug DARVOCET was manufactured.

97. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants is therefore strictly liable for the injuries sustained by the Plaintiff.

98. The Plaintiff could not by the exercise of reasonable care, have discovered DARVOCET's defects herein mentioned and perceived its danger.

99. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences and the Defendants failed to adequately warn of said risks.

100. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

101. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, inter

alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences, and they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote its product, DARVOCET.

102. By reason of the foregoing, the Defendants became strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, DARVOCET.

103. Defendants' defective design, manufacturing defect, and inadequate warnings of DARVOCET were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

104. That said defects in Defendants' drug DARVOCET were a substantial factor in causing Plaintiff's injuries.

105. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

106. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

107. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
THIRD CAUSE OF ACTION
AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)**

108. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

109. Defendants expressly warranted that DARVOCET was safe and well accepted by users.

110. The prescription pain management medication DARVOCET does not conform to these express representations because DARVOCET is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

111. Plaintiff did rely on the express warranties of the Defendants herein.

112. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of DARVOCET as prescription pain medication in recommending, prescribing, and/or dispensing DARVOCET.

113. The Defendants herein breached the aforesaid express warranties, as its drug DARVOCET was defective.

114. Defendants expressly represented to Plaintiff, her physicians, healthcare providers,

and/or the FDA that DARVOCET was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other prescription pain management medications, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

115. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that DARVOCET was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

116. As a result of the foregoing acts and/or omissions the Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

117. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the potential of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' drug DARVOCET.

118. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

119. By reason of the foregoing, Plaintiff has been damaged as against the Defendants

in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
FOURTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)**

120. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

121. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET, for use as a prescription pain management medication.

122. At the time Defendants marketed, sold, and distributed DARVOCET for use by Plaintiff, Defendants knew of the use for which DARVOCET was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

123. The Defendants impliedly represented and warranted to the users of DARVOCET and their physicians, healthcare providers, and/or the FDA that DARVOCET was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

124. That said representations and warranties aforementioned were false, misleading, and inaccurate in that DARVOCET was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

125. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

126. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether DARVOCET was of merchantable quality and safe and fit for its intended use.

127. The prescription pain management medication DARVOCET was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the product and accompanying materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

128. The Defendants herein breached the aforesaid implied warranties, as its drug DARVOCET was not fit for its intended purposes and uses.

129. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

130. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

131. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
FIFTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)**

132. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, DARVOCET, had been tested and was found to be safe and/or effective for prescription pain management.

134. The representations made by Defendants were, in fact, false.

135. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

136. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, DARVOCET, for use as a means of prescription pain management, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

137. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used DARVOCET, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

138. In reliance upon said representations, the Plaintiff was induced to and did use DARVOCET, thereby sustaining severe and permanent personal injuries, and being at an increased risk of sustaining severe and permanent personal injuries, and being at an increased risk of premature death.

139. Defendants knew and were aware or should have been aware that DARVOCET had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

140. Defendants knew or should have known that DARVOCET had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

141. Defendants brought DARVOCET to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

142. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

143. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

144. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
SIXTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)**

145. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

146. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of DARVOCET for its intended use.

147. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the risk of cardiotoxicity caused by DARVOCET.

148. Defendants knew or were reckless in not knowing that its representations were false.

149. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that DARVOCET was not as safe as other forms of pain management;
- (b) that the risks of adverse events with DARVOCET were higher than those with other prescription pain management medications;
- (c) that the risks of adverse events with DARVOCET were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in DARVOCET, in addition to and above and beyond those associated with other prescription pain management medications;

- (e) that DARVOCET was defective, and that it caused dangerous side effects, including but not limited to higher incidence of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, in a much more and significant rate than other prescription pain management medications;
- (f) that patients needed to be monitored more regularly than normal while using DARVOCET;
- (g) that DARVOCET was manufactured negligently;
- (h) that DARVOCET was manufactured defectively;
- (i) that DARVOCET was manufactured improperly;
- (j) that DARVOCET was designed negligently;
- (k) that DARVOCET was designed defectively; and
- (l) that DARVOCET was designed improperly.

150. Defendants was under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of DARVOCET, including but not limited to the heightened risks of an adverse cardiovascular event, such as a heart arrhythmia, myocardial infarction or sudden death.

151. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used DARVOCET, including the Plaintiff, in particular.

152. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of DARVOCET was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and their physicians, hospitals and healthcare providers into reliance, continued use of DARVOCET, and actions thereon, and to cause them to purchase, prescribe, and/or dispense DARVOCET and/or use the product.

153. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding DARVOCET, as set forth herein.

154. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

155. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

156. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

157. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
SEVENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)**

158. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

159. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, DARVOCET, had been tested and found to be safe and effective for prescription pain management.

160. The representations made by Defendants were, in fact, false.

161. Defendants failed to exercise ordinary care in the representation of DARVOCET, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented DARVOCET's high risk of unreasonable, dangerous side effects.

162. Defendants breached its duty in representing DARVOCET's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

163. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that DARVOCET had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for

lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

164. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

165. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**AS AND FOR THE
EIGHTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)**

166. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

167. Defendants conducted research and/or had a duty to conduct research using DARVOCET as part of its research.

168. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that DARVOCET was safe and effective for use as a means of pain management.

169. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

170. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

171. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and/or all other commercial media contained material representations of fact and/or omissions.

172. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug DARVOCET was safe and effective for use as a prescription pain management medication.

173. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug DARVOCET carried the same risks, hazards, and/or dangers as other prescription pain management medications.

174. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug DARVOCET was more effective for pain management, thereby encouraging the use of DARVOCET in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risk associated with DARVOCET.

175. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that DARVOCET was not injurious to the health and/or safety of its intended users.

176. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that DARVOCET was as potentially

injurious to the health and/or safety of its intended as other prescription pain management medications.

177. These representations were all false and misleading.

178. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that DARVOCET was not safe as a means of pain management and/or was not as safe as other means of pain management, including but not limited to other forms of prescription pain management medications.

179. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of DARVOCET, specifically but not limited to DARVOCET not having dangerous and serious health and/or safety concerns.

180. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiff, regarding the safety of DARVOCET, specifically but not limited to DARVOCET being as safe a means of pain management as other prescription pain management medications.

181. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of DARVOCET and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use DARVOCET.

182. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that DARVOCET was fit and safe for use as a prescription pain management medication.

183. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that DARVOCET was fit and safe for use as pain management and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other prescription pain management medications.

184. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that DARVOCET did not present serious health and/or safety risks.

185. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that DARVOCET did not present health and/or safety risks greater than other prescription pain management medications.

186. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

187. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe DARVOCET.

188. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of DARVOCET to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other prescription pain management medications.

189. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of DARVOCET by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of DARVOCET.

190. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on DARVOCET and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

191. Defendants, through its public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

192. Defendants utilized direct to consumer advertising to market, promote, and/or advertise DARVOCET.

193. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of pain management and were thereby induced to purchase, use and rely on Defendants drug DARVOCET.

194. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of DARVOCET.

195. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

196. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of DARVOCET, Plaintiff would not have purchased, used and/or relied on Defendants' drug DARVOCET.

197. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

198. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

199. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

200. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

AS AND FOR THE
NINTH CAUSE FO ACTION
AGAINST DEFENDANTS
(LOSS OF CONSORTIUM)

201. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

202. Plaintiff PHILIP ALIX was and is the lawful spouse of JEAN ALIX, and as such, was entitled to the comfort, enjoyment, society and services of his spouse.

203. As a direct and proximate result of the foregoing, Plaintiff PHILIP ALIX was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff JEAN ALIX, and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

204. For the reasons set forth herein, Plaintiff PHILIP ALIX suffered and will continue to suffer the loss of his loved one's support, companionship, services, society, love and affection.

205. By reason of the foregoing, Plaintiff PHILIP ALIX has been damages by the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

PRAYER FOR RELIEF


WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, and loss of consortium, together with interest and costs as provided by law;
2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
3. Awarding Plaintiff reasonable attorneys fees;
4. Awarding Plaintiff the costs of these proceedings; and
5. Such other and further relief as this Court deems just and proper.

Dated: Port Washington, New York
March 24, 2011

Respectfully submitted,

PARKER WAICHMAN ALONSO LLP

By: 
Matthew J. McCauley (MM-9610)
Six Harbor Park Road
Port Washington, New York 11050-4647
Telephone: (516) 466-6500
Facsimile: (516) 723-4730
Email: mmccauley@yourlawyer.com

Attorneys for Plaintiffs Jean Alix and Philip Alix

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
★ MAR 24 2011 ★

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

BROOKLYN OFFICE

-----X
JEAN ALIX and PHILIP ALIX,

Civil Action
Index No.:

Plaintiffs,

DEMAND FOR JURY TRIAL

-against-

ELI LILLY AND COMPANY, XANODYNE
PHARMACEUTICALS, INC., VINTAGE
PHARMACEUTICALS, INC., QUALITEST
PHARMACEUTICALS, and ENDO
PHARMACEUTICALS, INC.

Defendants.
-----X

CV 11 - 1456

BIANCO, J.

TOMLINSON, M.J.

Plaintiff hereby demands trial by jury as to all issues.

Dated: Port Washington, New York
March 24, 2011

Respectfully submitted,

PARKER WAICHMAN ALONSO LLP

By: 

Matthew J. McCauley (MM-9610)
Six Harbor Park Road
Port Washington, New York 11050-4647
Telephone: (516) 466-6500
Facsimile: (516) 723-4730
Email: mmccauley@yourlawyer.com

Attorneys for Plaintiffs Jean Alix and Philip Alix